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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,122	12/30/2003	Richard L. Boyd	NOR-014CP4 and 286336.153	3280

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EXAMINER	
MONTANARI, DAVID A	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	04/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/13/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/749,122	BOYD, RICHARD L.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/26/2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 26-34,36-44,46-70,73-75 and 79-84 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 26-34, 36-44, 46-70, 73-75, and 79-84 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 26-31, 54-58, 67-70 and 83, drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a virus, classified in class 424, subclass 93.1.

II. Claims 26-31, 54-55, 59-61, 67-70 and 83, drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a bacterium, classified in class 424, subclass 93.1.

III. Claims 26-31, 54-55, 62-64, 67-70 and 83, drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a parasite, classified in class 424, subclass 93.1.

IV. Claims 26-31, 54-55, 65-70 and 83, drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a fungus, classified in class 424, subclass 93.1.

V. Claims 26, 32-34, 36-40, 81 and 83, drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus and further comprising administering cells to the patient, classified in class 424, subclass 93.1.

VI. Claims 26, 41, 48 and 82-83, drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus wherein the thymus is reactivated by surgical castration, classified in class 128, subclass 1+.

VII. Claims 26, 41-44, 46-47 and 82-83, drawn to a method for preventing or treating

a disease in a patient comprising reactivating the thymus, wherein the thymus is reactivated by disruption of sex steroid-mediated signaling to the thymus and further comprising administering cells to the patient, classified in class 424, subclass 93.1.

VIII. Claims 26, 41, 49 and 82-83, drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus wherein the thymus is reactivated by chemical castration, classified in class 600, subclass 1+.

IX. Claims 26, 41, 50-54 and 82-84, drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus wherein the thymus is reactivated by a pharmaceutical, classified in class 514, subclass 2+.

X. Claims 26-31, 73-75 and 83, drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus and further comprising administering a cytokine, a growth factor or a combination of a cytokine and a growth factor, classified in class 424, subclass 198.1.

XI. Claim 79, drawn to a method for enhancing transplantation of donor hematopoietic stem cell into the thymus of a recipient patient, classified in class 424, subclass 93.1.

XII. Claim 80, drawn to a method for increasing virus-specific peripheral T cell responsiveness of a patient with an at least partially atrophied thymus, classified in class 424, subclass 93.1.

Group I is distinct from Groups II-XII. Group I is drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a virus. Groups II-XII are distinct from Group I because they comprise further steps over Group I, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group I. Further the etiology of how the disease is caused would require a distinct search for the pathology that results from the offending disease causing agent.

Group II is distinct from Groups I and III-XII. Group II is drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a bacterium. Groups I and III-XII are distinct from Group II because they comprise further steps over Group II, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group II. Further the etiology of how the disease is caused would require a distinct search for the pathology that results from the offending disease causing agent.

Group III is distinct from Groups I-II and IV-XII. Group III is drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a parasite. Groups I-II and IV-XII are distinct from Group III because they comprise further steps over Group III, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of

Group III. Further the etiology of how the disease is caused would require a distinct search for the pathology that results from the offending disease causing agent.

Group IV is distinct from Groups I-III and V-XII. Group IV is drawn to a method for preventing or treating disease in a patient comprising reactivating the thymus, wherein the disease is caused by a fungus. Groups I-III and V-XII are distinct from Group IV because they comprise further steps over Group IV, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group IV. Further the etiology of how the disease is caused would require a distinct search for the pathology that results from the offending disease causing agent.

Group V is distinct from Groups I-IV and VI-XII. Group V is drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus and further comprising administering cells to the patient. Groups I-IV and VI-XII are distinct from Group V because they comprise further steps over Group V, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group V. Further the second administration of cells would present a further distinct set of protocols that would require further search.

Group VI is distinct from Groups I-V and VII-XII. Group VI is drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus wherein the thymus is

reactivated by surgical castration. Groups I-V and VII-XII are distinct from Group VI because they comprise further steps over Group VI, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group VI. Further the surgical method of castration would present a further distinct set of protocols that would require further search.

Group VII is distinct from Groups I-VI and VIII-XII. Group VII is drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus, wherein the thymus is reactivated by disruption of sex steroid-mediated signaling to the thymus and further comprising administering cells to the patient. Groups I-VI and VIII-XII are distinct from Group VII because they comprise further steps over Group VII, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group VII. Further the second administration of cells would present a further distinct set of protocols that would require further search.

Group VIII is distinct from Groups I-VII and IX-XII. Group VIII is drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus wherein the thymus is reactivated by chemical castration. Groups I-VII and IX-XII are distinct from Group VIII because they comprise further steps over Group VIII, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group VIII. Further the chemical method of castration would present a further distinct set of protocols that would require further search.

Group IX is distinct from Groups I-VIII and X-XII. Group IX is drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus wherein the thymus is reactivated by a pharmaceutical. Groups I-VIII and X-XII are distinct from Group IX because they comprise further steps over Group IX, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group IX. Further the reactivation of the thymus by a pharmaceutical would present a further distinct set of protocols that would require further search.

Group X is distinct from Groups I-IX and XI-XII. Group X is drawn to a method for preventing or treating a disease in a patient comprising reactivating the thymus and further comprising administering a cytokine. Groups I-IX and XI-XII are distinct from Group X because they comprise further steps over Group X, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group X. Further the reactivation of the thymus by a cytokine would present a further distinct set of protocols that would require further search.

Group XI is distinct from Groups I-X and XII. Group XI is drawn to a method for enhancing transplantation of donor hematopoietic stem cell into the thymus of a recipient patient. Groups I-X and XII are distinct from Group XI because they comprise further steps over Group XI, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group XI. Further the method of transplantation would present a further distinct set of protocols that would require further search.

Group XII is distinct from Groups I-XI. Group XII is drawn to a method for increasing virus-specific peripheral T cell responsiveness of a patient with an at least partially atrophied thymus. Groups I- XI are distinct from Group XII because they comprise further steps over Group XII, and are drawn to entirely different methods of delivery or have distinct scopes that require materially distinct and separate protocols from the method of Group XII. Further the method of increasing virus-specific T cell response would present a further distinct set of protocols that would require further search.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

I n the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required is different among each group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630